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POLICY

The Federal Controlled Substances Act and Federal regulations establish important laws and regulations governing the purchase, receipt, storage and dispensing of controlled substances. This policy outlines the processes and procedures which must be followed in order to comply with Federal law, in regards to all control substance related activity.

SCOPE

This policy and procedure applies to all CVS/pharmacy Retail Stores.

GENERAL REQUIREMENTS

Controlled substances are drugs that have a high potential for addiction and abuse. As a result, the manufacturing, possession, and/or use of controlled substances are strictly regulated by Federal and State governments. All CVS Caremark colleagues are responsible for compliance with Federal and State controlled substances laws and regulations. All personnel involved in ordering, receiving, storing, dispensing, or otherwise disposing of controlled substances will receive ongoing training on controlled substances procedures.

1. RECORD KEEPING

Every pharmacy must maintain complete and accurate records that comply with all applicable laws and regulations governing the content, manner and period of retention for controlled substance records.

- Schedule II Controlled Substance prescriptions and records must be separated from Schedule III-V controlled substance prescriptions and records
- All Schedule III-V Controlled Substance prescriptions must be separated from all non scheduled drug prescriptions
- Controlled substance records must be kept separate from all other records
- All prescriptions must be filed in numerical order
- Federal law requires that a pharmacy keep controlled substance **records on site in the Pharmacy for two (2) years; however CVS has an internal record retention policy that required records are to be kept on site longer.** The records retention schedule can be viewed by clicking the link at the bottom of this section. The following records are to be stored in the pharmacy's Regulatory Records Box:
    - Executed DEA 222 forms (or the electronic equivalent)

- POA authorizations and Licenses
- Receipts and/or invoices for schedules II, III, IV, and V controlled substances
- Controlled substance inventory records, including the Initial, Annual, Biennial, Newly Scheduled Controlled Substance, Change of PIC, Acquired Inventory and Cycle Count Inventories
- Controlled substance distribution records (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
- Controlled substance dispensing records (i.e., prescriptions, schedule V logbook)
- Initial Notifications and DEA 106 forms
- DEA 41 forms (Inventory of Drugs Surrendered for Disposal)
- Records of transfers of controlled substances between pharmacies
- DEA registration certificate (If not required to be posed in your state)
- PSE Manifests
- Other State Required Records (ex: DHEC, DPS, BNDD)
- Miscellaneous (ex: BOP/DEA waiver requests to store records offsite, BOP remodel applications, Forged and Altered Prescriptions, etc.)

- **Some state regulations are more stringent than Federal regulations; in these cases the state requirement must be followed.**
  - It is the responsibility of all Pharmacy colleagues, and particularly the Pharmacy Manager, to be aware of the applicable state recordkeeping requirements
  - If you have any questions regarding state recordkeeping requirements, you may send your question to PharmacyOperations@cvscaremark.com
    Reference: CVS/Pharmacy Record Retention Schedule

2. DEA 222 FORM INFORMATION

DEA 222 Forms are issued in multiples of seven and sequentially numbered. When the forms are received, they must be counted and the order form serial numbers must be verified.

- Order forms cannot be used unless they contain the correct pharmacy name, address, and registration number
  - Forms that cannot be used because of a change in the name or location of the pharmacy must be returned to the DEA regional office
  - If your store receives 222 forms that do not reflect your store's correct information, such as the address and DEA number, the order forms may not be used. The local DEA office must be notified of the incorrect forms, and the forms returned to avoid accidental use
- Unexecuted order forms must be stored in the CII safe to prevent loss or theft
- Form 222a is used to requisition additional DEA Forms 222. This form can be found at:
  - https://www.deadiversion.usdoj.gov/webforms/orderFormsRequest.jsp
- DEA 222 forms must be executed in the sequential order of their serial numbers. Forms must be legibly completed (no cross-outs or write-over's) since suppliers are not permitted by law to fill orders submitted on illegible or altered order forms
  - **Reference:** Ordering and Receiving CII Drugs on the DEA 222 form
- Lost or stolen DEA Forms 222 must be reported to the local DEA Diversion Field office. The Pharmacist must also immediately notify the Pharmacy Supervisor and Regional Loss Prevention Manager

- When reporting the theft or loss of a DEA 222 form, the Pharmacist must include the serial numbers of each lost or stolen order form

- If an order form is lost in transit after it has been executed and sent to the wholesaler or manufacturer (e.g., order form lost in the mail enroute to the wholesaler or manufacturer), a new order form is required. DEA does NOT need to be notified
  - The Pharmacist must complete a second order form so the supplier can fill the original order
  - The pharmacy must attach a statement to the new order form that contains the following information:
    - The serial number of the lost order form
    - The date on the lost form
    - A statement that the drugs were never received
  - Make two copies of the lost order form statement.
    - Attach the original to copy 3 (the retained copy) of the lost order form
    - Attach one copy to the replacement order form copies 1& 2 when sent to the wholesaler or manufacturer
    - Executed DEA 222 Forms must be kept with the CII invoices and stored in the Regulatory Records box

3. ORDERING SCHEDULE II CONTROLLED SUBSTANCES

- Only the Pharmacist(s) who have power of attorney are authorized to place orders for Schedule II Controlled Substances
  - **Reference:** Pharmacists in Charge and Powers of Attorney at CVS/Pharmacy Retail Stores policy – Power of Attorney section
- If a Pharmacist with power of attorney is not available to sign the DEA Form 222, the store may not order Schedule II drugs
- All Federal Schedule II Controlled Substances must be purchased using the DEA Form 222. If the state you are located in also requires an order form for a state schedule II controlled substances, a DEA 222 form may be used
  - DEA 222 forms must contain the correct pharmacy name, address, and registration number
  - **Reference:** Ordering and Receiving CII Drugs on the DEA 222 form

4. RECEIVING SCHEDULE II CONTROLLED SUBSTANCES

Upon receipt of Schedule II Controlled Substances, a Pharmacist must physically count all items received. If the full amount of the controlled substances reflected on the invoice is not received in the order, the Pharmacist MUST refuse the entire order and send it back to the wholesaler.

- If the full amount of controlled substances reflected on the 222 form are contained in the order being received, the Pharmacist is required to conduct the following actions on the retained copy (copy 3) of the DEA Form 222:
  - Enter the amount received for each item listed on each line of the 222 form
  - Date each line for each item received on the 222 form
  - Sign the 222 form

- Do not use ditto marks or arrows
- A separate file of invoices and executed DEA 222 forms for Schedule II controlled substances must be maintained in the Regulatory Records box for a minimum of two (2) years
- Date and quantity received must also be entered into the perpetual inventory
  If a discrepancy exists between the amount received and the invoice quantity, the discrepancy must be investigated immediately. Resolutions must be documented
- **Reference:** Reporting Theft Or Loss Of Controlled Substances/PSE/E Listed Chemicals policy
- **Reference:** Ordering and Receiving CII Drugs on the DEA 222 form

5. ORDERING SCHEDULE III – V CONTROLLED SUBSTANCES

- Ordering Schedule III, IV, and V Controlled substances must occur in accordance with non-scheduled medication purchasing procedures at the discretion of the Pharmacist in Charge
- The AIMRx Order Detail Report is a complete listing of all CVS Warehouse replenished items AIMRx is going to automatically order
  - It is available first thing in the morning on the store's Warehouse Poll (Order) Day from the Pharmacy Computer System
  - The person in charge of ordering must carefully review the AIMRx Order Detail Report to ensure order accuracy paying special attention to:
    - Any item with an unusually high or low quantity Balance on Order (BOO)
    - Items with unusually high or low inventory at store level Balance on Hand (BOH)
      - **Reference:** AIMRx Order Detail Report working instructions on RxNet

6. RECEIVING SCHEDULE III-V CONTROLLED SUBSTANCES

- Upon receipt of Schedule III-V substances all medications must be checked in piece by piece against the Invoice by the Pharmacist/Pharmacy Technician
- Each invoice (both CVS Warehouse shipments and OV shipments), must contain the following elements:
  - Symbol to show receipt of each quantity of product received
  - The date of receipt must be handwritten on the invoice
  - The Pharmacist's or Technician's signature to signify that the amount listed on the invoice was received in the pharmacy
- The invoice must then be kept in the Regulatory Records box. The CIII-CV invoices must be kept separately from the CII invoices in the proper folders
- If there is a discrepancy between the invoice and the order for an OV order, the pharmacy must refuse the order and return it to the OV (see below for details)
- If there is a discrepancy with a DC order, call Distribution Services at 401-770-5555 (see below for details)
- Any discrepancies between the amount received and the invoice quantity must be investigated immediately. Resolutions must be documented

- **Reference:** Reporting Theft Or Loss Of Controlled Substances/PSE/E Listed Chemicals policy

- The order must be stored immediately in the designated areas of the pharmacy including pharmacy shelves, cabinets, safe, or refrigerator
  - Schedule III-V controlled substances will be kept dispersed throughout the non-controlled inventory in a limited-access area of the pharmacy, except for those products to be kept in the Hydrocodone safe
- **Reference:** Pharmacy Warehouse Delivery policy – Checking In Warehouse Deliveries section

7. STORAGE AND SECURITY OF CONTROLLED SUBSTANCES

- After receipt and confirmation of the amount received, the controlled substances must be stored immediately in the designated areas of the pharmacy to include shelves, cabinets, safe, or refrigerator
  - Schedule II Controlled substances will be stored in the securely locked designated Schedule II safe. Only registered Pharmacists may have access to the Schedule II safe. The safe must be kept locked
    - Items other than Schedule II medication and unused DEA 222 forms are not to be kept in the Narcotic safe or Narcotic cabinet. Schedule III-V medications may be stored in the safe only at the recommendation and approval of Loss Prevention or your Pharmacy Supervisor or as stated as a security measure from a submitted DEA 106 form. Under no circumstances are non-controlled medications to be kept in the narcotic safe or narcotic cabinet. In the event Schedule III-V medications are approved to be stored in the safe, the same security measures as for Schedule II must be taken for all contents; only Pharmacists are permitted to have access to the medications in the safe
  - Schedule III, IV, and V controlled substances will be kept dispersed throughout the non-controlled inventory in a limited-access area of the pharmacy unless instructed otherwise by Pharmacy Operations
- The Pharmacy Manager must comply with all storage requirements of their State Board of pharmacy
- Only registered Pharmacists may have keys, combinations or codes, to safes, refrigerators, cabinets, or alarms where controlled substances are located
- Each Pharmacist while on duty shall be responsible for the security of all drugs held within the pharmacy
- Every pharmacy must have an alarm system that is designed to provide coverage to all areas where all medications including controlled substances are stored when the pharmacy is closed
  - **Reference:** Pharmacy Access and Security policy

8. DEA REQUIRED INVENTORIES AND DOCUMENTATION

Federal law requires all Pharmacies complete a Biennial controlled substance inventory. However, many states have more stringent regulations that require controlled substance

inventories on an annual basis. Additionally, Pharmacy Supervisors must ensure a controlled substance inventory is performed for any Changes in Pharmacist-in-Charge (PIC) or Change of Ownership due to an Acquisition, or acquisition of inventory from a target store in a file-buy or store-buy.

- The Annual and Biennial inventories must be completed on the same date each year either after closing on April 30 or before opening on May 1, unless required by your State. Click HERE to access the listing of states requiring an Annual inventory
- The change of PIC must occur prior to the start of dispensing by the new PIC
- In 24 hour stores the inventory must be completed during the overnight hours between midnight and 6am on May 1
- There must not be any dispensing of controlled substances during this time period
- All newly licensed pharmacies and newly assigned Pharmacy Manager/PIC's must complete an initial inventory of all controlled substances
- A biennial inventory of all controlled substances is required, or more frequently as required by State law
- All Inventories must contain the following information:
    - Type of inventory (Biennial, Annual, or Change of Pharmacy Manager/PIC)
    - The name, address, and DEA registration number of the pharmacy
    - The date and time of the inventory (Open or Close the business day)
    - The inventory must separate out CII drugs from CIII-CV drugs
    - The names of all controlled substances
    - The dosage form and unit strength of each controlled substance
    - The number of units or volume in each container of controlled substances
    - The number of commercial containers of each controlled substances
    - If no controlled substances are on hand at the time of the inventory, the Pharmacist must record an inventory stating that no controlled substances are in inventory
        - Some states require PSE, Butalbital products, and/or Drugs of Concern products to be included in the inventory. Click HERE to access the State specific requirements

The Pharmacist in Charge is responsible for the accurate and timely completion of all required Controlled Substance Inventories:

- Click HERE to view your **state-specific requirements** for the Annual/Biennial Controlled Substance Inventory
- Click HERE to access the Controlled Substance Inventory requirements and RF Unit process steps
- The complete inventory and attached cover sheet must be stored in the Regulatory Records Box
    - As required by Federal regulations, inventories must be retained on site for two(2) years, unless longer retention is required by the state
    - Schedule II controlled substance inventories must be maintained separately from Schedule III-V controlled substance inventories
        - Each inventory must have its own coversheet with the required information in order to be compliant

- Inventories must include all State and federally scheduled drugs on hand at the time each inventory is conducted. This includes controlled substances in the waiting bin, refrigerators and freezers, in quarantine, and awaiting return to Genco and StrongPak
- Each controlled substance inventory must be maintained separate from all non-scheduled medication documentation
- **Reference:** Controlled Substance Inventory

9. PERPETUAL AND MONTHLY INVENTORY REQUIREMENTS AND DOCUMENTATION

9.1 PERPETUAL:

- Every transaction, including receipt, dispensing, and returns, involving a Schedule II controlled substance will be recorded in a perpetual inventory
- All waste and outdated controlled substances awaiting destruction must be included in the inventory
- The Perpetual Inventory Form will contain, at a minimum, the following information:
  - The drug name
  - Strength or concentration of each dosage form.
  - Dosage form
  - Manufacturer
  - Storage requirements
  - Transaction dates
  - Patient's or supplier's name
  - Prescription number or DEA Form 222 serial number
  - Amount added or subtracted
  - Balance at the end of the transaction
  - Initials of the Pharmacist
    - The following is a list of the items number available for the Perpetual Inventory Logs:
      - Item # 984237 – CII Inventory Log
      - Item # 902245 - Controlled Substances Perpetual Inventory Log – Spanish - Puerto Rico stores only
      - Item # 935644 - Controlled Substances Perpetual Inventory Log – Spanish -West Virginia stores only
- Retain the perpetual inventory on site in the pharmacies' CII Binder for a minimum of two (2) years or as long as mandated by your state
- Any discrepancies must be investigated immediately. If controlled substances cannot be accounted for, follow the loss/theft reporting process
  - **Reference**: Reporting Theft Or Loss Of Controlled Substances/PSE/E Listed Chemicals policy

9.2 MONTHLY INVENTORIES:

- A complete count of all Schedule II drugs will be performed once a month and recorded in the perpetual inventory

- At the discretion of the Pharmacy Manager, management, or as required by state law inventories may be conducted more frequently
- Any discrepancies must be investigated immediately. If controlled substances cannot be accounted for, follow the loss/theft reporting process
    - **Reference**: Reporting Theft Or Loss Of Controlled Substances/PSE/E Listed Chemicals policy

10. THEFT OR LOSS REPORTING PROCEDURE

Click to view the policy from the Pharmacy Operations manual: Reporting Theft Or Loss Of Controlled Substances/PSE/E Listed Chemicals

- If you have any questions regarding theft/loss reporting, you may send your question to RxRegulatory@CVSCaremark.com

11. LOST IN TRANSIT (In-Transit Losses)

Click to view the policy from the Pharmacy Operations manual: Reporting Theft Or Loss Of Controlled Substances/PSE/E Listed Chemicals - In-Transit Losses section

- If you have any questions regarding theft/loss reporting, you may send your question to RxRegulatory@CVSCaremark.com

Shipping from the pharmacy to a reverse distributor (i.e. GENCO):

- If a shipment of controlled substances is lost in transit from the pharmacy to a reverse distributor and the pharmacy is notified by UPS or GENCO of the loss, the Pharmacy Supervisor and RLPM must be notified immediately so that an investigation can be launched
- The pharmacy (as the supplier) is responsible for filing an Initial Notification within 24 hours unless the reverse distributor signed for the delivery
- If the reverse distributor signed for the delivery, then the reverse distributor is responsible for notifying DEA. However, CVS Caremark shall cooperate with the investigation being performed by the reverse distributor
- **Reference:** Return of Class II Control Substances to GENCO Pharmaceutical Services, Inc. policy - GENCO Pharmaceuticals Services (GPS) – Shortages

12. SCHEDULE III – V RETURNS

- When the Pharmacy is returning Scheduled III-V Controlled Substances to a reverse distributor the pharmacy must maintain a record of distribution that lists the drug name, dosage form, strength, quantity, and date transferred
- Any CIII-CV or Non-Controlled Items which are in an Original Manufacturer's Container (Stock Bottle, Tube of Cream, Box of Patches, Insulin Vial, etc.) can be returned to GENCO, except for containers that are leaking or a reconstitute that has already been mixed
    - All protected health information (PHI) must be removed prior to placement in the GENCO box

- Rx Returns cardboard box must always be used to ship items; this box does not have any reference to pharmaceutical items or vendors
- UPS shipping labels are printed from the GENCOSmart system the next day after return is entered
- Each box is sealed securely with the clear packing tape along both the top and bottom seams
- The UPS shipping label is affixed to the correct cardboard box immediately after it is printed from the GENCOSmart system
  - **Reference:** Work Instructions titled Returns Management Best Practices on RxNet

13. SCHEDULE II RETURNS

Click to view the policy from the Pharmacy Operations manual: Return of Class II Control Substances to GENCO Pharmaceutical Services, Inc.

- **Reference:** Work Instructions titled Schedule II GENCO Returns on RxNet

14. DISPENSING CONTROLLED SUBSTANCES

All dispensing of controlled substances must comply with federal and state laws and regulations.

- CVS Pharmacists are not permitted to fill and dispense Controlled Substances issued for themselves or family members
- CVS Pharmacists must not fill Controlled Substance prescriptions that are written by a prescriber for themselves or for their family members
  - Family Members are defined as a spouse, parent, child, sibling or other individual in relation to whom a Pharmacist/Prescriber's personal or emotional involvement may render that physician unable to exercise detached professional judgment in reaching diagnostic or therapeutic decisions
- CVS Pharmacists must not fill Controlled Substance prescriptions where the prescriber wishes to use the prescription to supply the prescriber with an inventory of drugs that the prescriber intends to administer/dispense to patients. Such prescriptions may appear to be written for the prescribers themselves, for their "office use," for a "doctor bag" or other similar patient designation

14.1 CORRESPONDING RESPONSIBILITY

DEA regulations require that a controlled substance prescription must be issued for a **legitimate medical purpose** by an individual practitioner, acting in the usual course of his/her medical practice.

- The initial responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner; however DEA regulations place **"corresponding responsibility"** on the Pharmacist who fills the prescription
- **Reference:** Guidelines for Dispensing Controlled Substances policy

14.2 CONTACTING PRESCRIBERS FOR CLARIFICATION

TITLE:	FEDERAL GUIDELINES FOR CONTROLLED SUBSTANCES

A controlled substance prescription is considered valid as long as both of the following requirements have been met.

- The prescription must have been issued for a legitimate medical purpose by a prescriber, acting in the usual course of his or her professional practice
- It contains all the Federal and applicable State requirements for a controlled substance prescription

If the Pharmacist has a question about a prescription, the Pharmacist **must** contact the prescriber for clarification and verification before filling the prescription.

- Where the prescriber is not familiar to the Pharmacist, the Pharmacist must attempt to independently locate the prescriber's contact information before resorting to any phone number listed on the prescription
- Conversation with the prescriber's office must be documented on the actual prescription and/or in RxConnect
    - For prescription clarifications, such as missing patient, prescriber, or drug information, the information must be written legibly on the hardcopy prescription. Additionally, the name of the person spoken to at the prescriber's office must be documented along with the date and time that the conversation occurred
    - For clinical questions concerning the patient and/or prescription, the information must either be documented on the hardcopy prescription or in RxConnect by utilizing the patient notes functionality
    - **Reference:** Accepting Prescriptions policy

Even if a prescriber indicates that the prescription should be filled as written, the Pharmacist must use his/her professional judgment to determine whether the prescription was issued for a legitimate medical purpose in the normal course of professional practice.

- Pharmacists are strongly encouraged to utilize their state's PMP for new prescriptions and for prescriptions of highly diverted drugs (e.g. Hydrocodone and Oxycodone)
    - If a state requires mandatory PMP checks, the Pharmacist on Duty must comply to the states requirements
    - **Reference:** Prescription Drug Monitoring Program policy

14.3 RED FLAGS

PATIENT RED FLAGS

- **Distance**
    - Either or both the patient and prescriber not being located within the store's geographic area (in most cases)
    - Patient traveling distances to pharmacy or doctor
- **Cash**
    - Cash payment for prescriptions, particularly if RxConnect indicates the patient has insurance
- **Suspicious Behavior**
    - Customers arriving in groups to get narcotic prescriptions filled
    - Customer requests specific drugs by brand name or description (e.g., M's, blues, Mallinckrodt blues)

- Customer appears to be visibly impaired, intoxicated or incoherent
- **Early Fills**
  - Customer attempting refill early or consistently showing up at the first available moment when refill can be obtained under standard practice
- **Doctor Shopping**
  - Evidence of multiple doctors prescribing controlled prescriptions for customer after review of profile or PMP data
- **Appropriateness of Therapy**
  - Patient remains on long-term high dose opioid long after injury has healed

PRESCRIBER RED FLAGS

- **Professional Practice**
  - Prescribes the same medication in the same dosage amount to most or all of their patients
  - Use of preprinted or stamped prescriptions
- **Cocktails**
  - Routinely prescribes the same combination of pain drugs for most or all of their patients
  - Prescribes combinations the DEA has identified as having a high potential for abuse (e.g., oxycodone, alprazolam and carisoprodol)
- **Scope of Practice**
  - Prescribing of narcotics does not fit with the prescriber's practice (e.g., ophthalmologist)
- **Appropriateness of Therapy**
  - Overprescribing large doses of controlled substances to patients

15. ACCEPTING SCHEDULE II (CII) PRESCRIPTIONS

If the prescription was written for a legitimate medical purpose, it must contain all required information including:

- Patient's full name and address
- Drug name, strength, dosage form and quantity
- Directions for use
- Prescriber's full name, address, and DEA registration number
  - When entering prescription information into RxConnect, all Pharmacy colleagues must ensure that correct prescriber information is entered. There can be multiple prescribers with similar names and you must make sure that the correct prescriber is identified and selected
- Manual signature of the prescriber

Reference: Accepting Prescriptions policy.

15.1 FAXED CII PRESCRIPTION

Faxed CII prescriptions may be filled and prepared; however, they are not to be dispensed until the Pharmacy receives the original, hard copy prescription.

Faxes can be accepted if the facility is a state-registered hospice location. Note that certain states require such prescriptions to feature a label or notation that they are intended for a hospice patient.

15.2 ORAL CII PRESCRIPTION

While emergency prescriptions should be an extremely rare occurrence, Federal law permits an emergency CII prescription to be phoned into the pharmacy, with the amount dispensed limited to a seventy-two (72) hour supply. The prescriber must follow up with a written prescription within **seven (7) days** unless state law is more restrictive; Pharmacists are responsible for knowing their state's particular requirements. The hardcopy prescription must have written on its face "Authorization for Emergency Dispensing," and the date of the oral order.

If the pharmacy does not receive the written prescription from the Prescriber within seven (7) days, the Pharmacy team must notify the local DEA office. Some states will have specific forms that are to be used for the notification and may require that state entities also be informed.

15.3 PARTIAL FILL OF CII PRESCRIPTION

A partial fill for CII is allowed if a Pharmacist cannot supply the full quantity written, provided that the Pharmacist notes the quantity on the prescription and the remaining portion is dispensed within seventy-two (72) hours.

- If the remaining portion cannot be dispensed within the seventy-two (72) hour period, the Pharmacist must notify the prescriber and get a new hard copy prescription

15.4 REFILLS OF CII PRESCRIPTION

Schedule II prescriptions may **not** be refilled. However, in some cases, DEA regulations allow practitioners to write multiple prescriptions for Schedule II drugs to be dispensed over a number of months:

- The total amount prescribed and dispensed pursuant to all of the prescriptions must be limited to a 90 day supply
- Each prescription must be issued on a separate prescription blank
- Each separate prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice
- The practitioner must provide written instructions on each prescription **indicating the earliest date the Pharmacy may fill the prescription**

Please note that some States do not permit multiple prescriptions for Schedule II drugs.*

16. ACCEPTING SCHEDULE III-V PRESCRIPTIONS

A Schedule III-V Prescription must contain all required information including:

- Patient's full name and address
- Drug name, strength, dosage form, and quantity
- Directions for use

- Number of authorized refills, if any
- Prescriber's full name, address, and DEA registration number
  - When entering prescription information into RxConnect, all Pharmacy colleagues must ensure that the correct prescriber information is entered. There can be multiple prescribers with similar names and you must make sure that the correct prescriber is identified and selected
- Manual signature of the prescriber

Reference: Accepting Prescriptions policy.

16.1 FAXED CIII-V PRESCRIPTION

Faxed prescriptions are acceptable as long as there is a manual signature of the prescriber; an electronic or typed signature is not valid.

16.2 ORAL CIII-CV PRESCRIPTION

An oral prescription is acceptable provided that the prescription is promptly reduced to writing by the Pharmacist and contains all information on a written prescription except for the signature of the prescriber. Verbal prescriptions are to be maintained with other prescriptions.

- Some States have more stringent regulations around oral prescriptions. In States where this is the case, the State regulation must be adhered to

16.3 REFILLS OF CIII-CV PRESCRIPTION

Schedule III through IV prescriptions may be refilled if authorized on the prescription. However, under federal law, the prescription may only be refilled five (5) times within six (6) months after the original date of issue, whichever comes first. Afterwards, a new prescription is required.

- State law may be more restrictive

Schedule V prescriptions may only be refilled if authorized on the prescription by the prescriber.

- Some states impose additional limits on control substance refills

17. BUPRENORPHINE (SUBUTEX OR SUBOXONE) PRESCRIPTIONS - OPIOD ADDICTION DRUGS

Physicians must include their DATA 2000 waiver ID number on prescriptions for opioid addiction treatment medications. The practitioner's DEA registration number and the unique identification number (DATA 2000 waiver ID number or "X" number) must be on the prescription.

- The identification number is not in lieu of the DEA registration number; it is an addition
- If the prescription is telephoned to the pharmacy, the Pharmacist must have both of these numbers on the prescription record so the physician can provide the numbers or the Pharmacist may have them on file

Note: For Buprenorphine/Suboxone prescriptions written for pain, the prescriber must indicate that the prescription is written for pain treatment.

- For pain prescriptions, no X ID number is required

18. PENALTIES FOR VIOLATION OF THIS POLICY/DISPENSING REGULATIONS

It is illegal to knowingly dispense a controlled substance pursuant to an invalid prescription. This includes prescriptions that:

- Are not issued for a legitimate medical purpose by a practitioner, acting in the usual course of professional practice and a prescription that does not meet the technical requirements (signature, date, DEA number, etc.)
- Violates limitations on oral, facsimile or electronic prescribing
- Appear to be altered, forged or copied

A Pharmacy colleague who fails to take steps to verify a prescription when there is reason to believe it is not valid and, instead, fills the questionable prescription, can be prosecuted criminally and/or lose his or her professional license in addition to being subject to disciplinary action by CVS/pharmacy up to, and including, termination of employment.

REMEMBER, WHEN BOTH FEDERAL AND STATE REGULATIONS APPLY; YOU MUST FOLLOW THE MORE STRINGENT REQUIREMENTS.

DEFINITIONS (All defined words in this document should be displayed with initial capitals, except for acronyms.)
N/A

REVIEW AND REVISION HISTORY

Date	Revision No.	Reason for Change	Sections Affected
10/1/2014	1.0	New Policy and Procedure	All